the Watchman (Boston Scientific, Marlborough, MA) is as effective as warfarin for the reduction the risk of stroke, systemic embolism and cardiovascular mortality in this population. A new generation of Watchman FLX (WM-FLX) has been designed to further improve implant performance. The key design changes in the WM-FLX include an increased number of struts, an a traumatic closed distal end, and a reduced length. The WM-FLX can be redeployed after either full or partial recapture. In contrast, the CG-WM has to be replaced if a full recapture is needed. The present study is aimed to evaluate the WM-FLX device in a canine LAA model.

METHODS AND RESULTS 20 dogs were used in the study. Under TEE at 0, 45, 90 and 135° views and x-ray guidance, the device was appropriately sized at the LAA ostium. Device deployment was attempted in all animals; of which 100% of WM-FLX (12/12) and 75% of CG-WM (6/8) were successfully deployed. Of the two unsuccessful implants, one was due to pericardial effusion and the other was due to unfavorable anatomy. All implanted animals survived to 45 or 90d. At termination, no thrombus was observed upon gross examination. Histopathology showed all of the devices to be well-seated in the LAA ostium at 45 and 90d, and covered by a layer of neo-endocardial tissue.

CONCLUSION The next generation Watchman FLX device has improved delivery, with fewer devices partial or full recaptures compared to the CG-WM. Furthermore, the WM-FLX device resulted in a better seal with no leaks compared to the CG-WM, though neither device showed residual leaks in excess of 2 mm. The healing response in WM-FLX was comparable to CG-WM, and no evidence of a safety risk was identified in either cohort at either time point.

Overall Implantation Parameters

	CG-WM	WM-FLX
Dogs	6	12
Total devices used	10	12
Full recaptures required	4	2
Partial recaptures	3	3
Peri-device jet (<2mm)	2	0

MITRAL VALVE

CRT-819

Immediate In-hospital Complications of Percutaneous Transvenous Mitral Commissurotomy in patients with Mitral Stenosis

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BACKGROUND Rheumatic mitral stenosis is a very common problem in our population having an incidence of 54 percent among rheumatic heart disease with a female preponderance of 2:1. Percutaneous balloon mitral commissurotomy is appealing because the mechanism of valve dilation closely parallels the mechanism of surgical mitral commissurotomy. The technique of balloon mitral commissurotomy has evolved rapidly, with improvements in balloons, guide wires, and the application of double-balloon techniques. So, we aimed to assess the immediate in-hospital complications of percutaneous transvenous mitral commissurotomy (PTMC) in patients with symptomatic moderate to severe rheumatic mitral stenosis in our population.

METHODS : A prospective study was done in National Institute of Cardiovascular Diseases, Dhaka, Bangladesh and Al- Helal Heart Institute, Mirpur, Dhaka during the period of August 2003 to June 2014. Nine hundred and ninety (990) patients with rheumatic mitral stenosis who underwent PTMC were evaluated clinically, by echocardiography and by catheter during and after procedure.

RESULTS After PTMC mean mitral valve area increased from 0.83 ± 0.11 cm2 to 1.76 ± 0.27 cm2 as measured by echocardiography. Mitral valve gradient reduced to 11.63 ± 4.15 mm Hg from 28.46 ± 03.94 mm Hg after PTMC. Mean left atrial pressure as recorded by catheter before PTMC was 30.99 ± 08.37 mm Hg while after PTMC it was 13.81 ± 06.28 mm Hg. There was no procedural death. There were 4 patients in-hospital death. 2 patients died from massive CVD after PTMC. 1 patient died from renal failure and electrolyte imbalance, 1 patient died from multisystem organ failure due to sepsis unrelated to PTMC. There were 2+ mitral regurgitation in 3 patients or 3+ post PTMC mitral regurgitation in 1 patient as assessed by left ventriculography. There was no A-V block during or after PTMC.

Pericardial tamponade occurred in 5 patients post procedure and those patients were successfully treated with pericardiocentesis in the catheterization laboratory under echo guidance and PTMC was completed successfully. Thromboembolic events occurred in 04 patients and in 2 patients massive CVD and in 2 patients TIA. Left to right shunt (ASD) occurred in 30 patients.

Local vascular complications like pain, hemorrhage, hematoma occurred in 69 patients.

CONCLUSION PTMC is a very effective and safe procedure at relieving the hemodynamic effects of rheumatic mitral stenosis. Complications during the procedure was very few.

CRT-820

25 Years Follow-up Of Percutaneous Mitral Balloon Valvotomy: Echocardiographic Score influence, Risk Factors For Death And Major Events

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Percutaneous mitral balloon valvotomy (PMBV) has emerged as an alternative to surgical treatment of mitral stenosis.

OBJECTIVES To identify the independents predictors of death and combined events (death, new mitral balloon valvotomy, or mitral valve surgery) in long-term follow-up of patients undergoing PMBV.

METHODS From 1987 to 2013 a total of 312 patients were followed-up 54.0±31.0 (1 to 126) months. The techniques were the single-balloon (84.4%), Inoue-balloon (13.8%), and double-balloon techniques (1.7%). The total group was divided in two: echocardiographic score >8 and ≤ 8 points groups. Multivariate Cox regression analysis were performed to identify independent risk factors of long-term survival and event free survival.

RESULTS The mean age were 38.0±12.6 years old (range, 13 to 83). Before the procedure, 84,42% patients had echo score ≤ 8, and 15.57% score> 8. Females comprised 85%, and 84% patients were in sinus rhythm. During follow-up, survival of the total group was 95.5%, echo score group ≤ 8 was 98.0% and echo score > 8 was 82.2% (p<0.0001), whereas combined event-free survival was 83.4%, 86.1%, and 68.9%, respectively (p 8 and the presence of severe mitral valve regurgitation during the procedure. The predictors of combined events were a previous history of mitral valvular commissurotomy, atrial fibrillation, the presence of severe mitral valve regurgitation during the procedure and post procedure mitral valve area < 1.5 m2.

CONCLUSION PMBV is an effective procedure. Survival was high, even higher in the group with lower echocardiographic scores. Over 2/3 of the patients were event-free at the end of follow-up. Independents predictors of survival were pre procedure echo score ≤ 8 and the absence of severe mitral valve regurgitation during the procedure.

CRT-821

Fully Percutaneous Transthoracic Left Atrial Access To Deliver Large Interventional Devices

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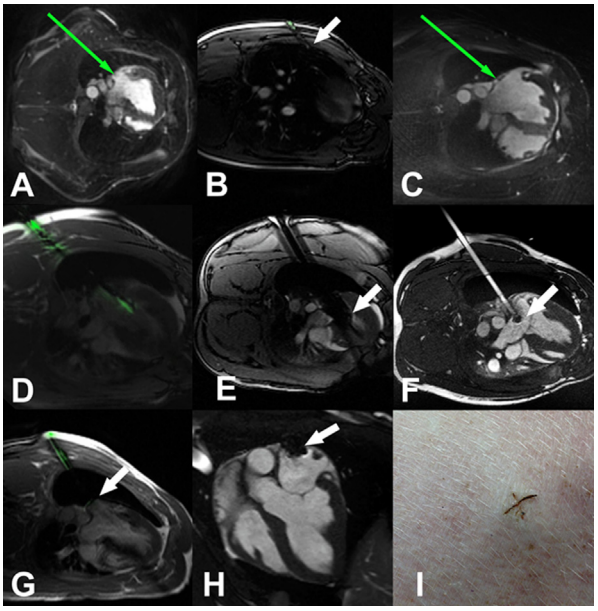
BACKGROUND Investigational transcatheter replacement mitral valves are bulky devices requiring large caliber access ports. An access route (Fig 1A) that does not impact left ventricular (LV) function could simplify device engineering and improve patient outcomes. We hypothesized that by deflating a lung, it is possible to access the left atrium (LA) through the posterior chest wall, and close the LA port using off-the-shelf nitinol closure devices.

METHODS LA access was obtained in 2 large animal models under realtime MR (8 swine and 2 sheep) or X-ray fluoroscopy (2 swine). A drain was inserted into the left pleural space to insufflate with CO2 and displace the lung (arrow, Fig 1B). A needle was introduced through the chest wall (Fig 1C) and into the LA posteriorly (Fig 1D). A large (18Fr) sheath (arrow, Fig 1E-F) was advanced into the LA over a stiff wire. The sheath was withdrawn and the LA puncture was closed with a nitinol closure device (arrow, Fig 1G). Animals were re-imaged 7days later.

RESULTS Pleural access, left lung deflation, LA access and closure, and lung re-inflation was successful in all 12 animals. There were no peri-procedural complications or mortality. After 7days, MRI confirmed stable position of the LA closure device in all (arrow, Fig 1H), only one pericardial effusion was observed and superficial wounds healed well (Fig 1I).

CONCLUSION Fully percutaneous MR guided direct LA access with large sheaths is feasible in swine and sheep, providing access to the mitral valve without injuring the LV myocardium. The LA port can be safely closed using off-the-shelf nitinol closure devices. This technique could provide a simple and safe access route for transcatheter mitral valve interventions.



OTHER

CRT-822

Support System of Bioprosthetic Valves With A Heart Shape Commissural Post

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BACKGROUND Bioprosthetic valves fail due to torn leaflets as a result of increased forces applied on the commissural posts during the cardiac cycle. To face this problem a novel Support System (stent) with large openings at the Commissural posts made from acetal copolymer (POM-C) or Titanium has been developed. The hydrodynamic performance and durability of bioprosthetic valves constructed using this stent went under evaluation.

METHODS This stent was initially designed to accommodate aortic and pulmonary valves derived from marine mammal origin (Phoca Groelandica), showing excellent hydrodynamic performance when tested in a steady flow system. The same stent was used to create three trileaflet composite porcine valves of 23mm (titanium), 27mm and 31mm (POM-C) in diameter and one 25mm (titanium) bovine pericardial valve wrapped around the stent. All valves were tested in a steady flow system. The three porcine valves underwent fatigue accelerating testing to define their long term durability.

RESULTS For the porcine valves the peak pressure was measured as 12.5mmHg, 9.1 mmHg and 7.3mmHg for the 23mm, 27mm and for the 31mm valve respectively. The 25mm pericardial valve showed a peak pressure of 5.5mmHg. The durability test showed valve deterioration after 225x106cycles for the 23mm, 265x106 cycles for the 27mm and 240x106 cycles for the 31 mm, values far above the passing standards according to ISO/DIS 5840.

CONCLUSION This novel stent for bioprosthetic valves offers excellent hydrodynamic performance for a variety of biological issues tested and above the standards long term durability, possibly due to the amelioration of forces applied on the commissural posts during the cardiac cycle.

CRT-823

Transcatheter Extra-Cardiac Tricuspid Annuloplasty

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BACKGROUND We designed and built a device that is positioned along the atrio-ventricular groove in the pericardial space and tightened to modify the geometry of the tricuspid annulus to treat functional tricuspid regurgitation. The device is delivered to the pericardial space from within via trans-atrial puncture.

METHODS 15 swine, including 3 with dilated right heart and functional tricuspid regurgitation, underwent extra-cardiac tricuspid annuloplasty. The pericardial space is accessed with large (12-14Fr) sheaths from a femoral vein, through the right atrium and by puncture through the right atrial appendage. A self-orienting nitinol compression device is then deployed around the atrioventricular groove and tightened to exert compressive force to the free-wall of the tricuspid annulus. The atrial puncture site is closed with an off-the-shelf nitinol closure device.

RESULTS In all 15 animals, trans-atrial pericardial access was uncomplicated and the device was delivered successfully. Tricuspid septal-lateral and antero-posterior dimensions, annular area and perimeter were reduced by 49%, 31%, 59% and 24% ($p<0.001$) respectively. Tricuspid leaflet coaptation length was increased by 53% ($p<0.001$). The degree of annuloplasty correlated closely with the tension delivered to the device ($r2=0.94$, $p<0.001$). Coronary artery compression was not observed in any animal, but a bridge-shaped protection element can be positioned over an underlying vessel to deflect compressive force. 9 animals were survived for mean 9.7days and tricuspid geometric changes were maintained. In the 3 animals with functional tricuspid regurgitation, severity of regurgitation by intracardiac echocardiography was reduced. Small pericardial effusions were observed immediately post-procedure but had completely resolved at follow-up. Post-mortem examination demonstrated fibrotic encasement of the device along the atrioventricular groove and no tissue erosion. There was no evidence of pericarditis or adhesions between visceral and parietal pericardial layers.

CONCLUSION This is the first extra-cardiac structural intervention performed from within via trans-atrial puncture. The degree of tricuspid annuloplasty achieved is comparable to current surgical techniques. The trans-atrial pericardial access port is safely closed with off-the-shelf devices, with no evidence of cardiac tamponade in swine.

CRT-824

Does Angio-Seal Have a Role in Femoral Vascular Closure Following Transcatheter Aortic Valve Replacement?

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BACKGROUND Femoral access closure post transcatheter aortic valve replacement (TAVR) remains challenging. The Perclose ProGlide (PP) device has been utilized in a dual pre-close strategy; however, failure of this technique occurs in approximately 10% of cases. This study examined the utility of Angio-Seal (AS) in selected cases where hemostasis is not achieved with the dual PP alone.

METHODS Patients who received a percutaneous transfemoral TAVR with the use of at least two PP and, given residual bleeding, subsequently received one AS device, were included. This cohort was divided into two groups: a success group (full hemostasis with two PP and one AS), and a failure group (required additional interventions). The baseline and procedural characteristics, in-hospital VARC-2 major and minor vascular access site and bleeding complications, change in hemoglobin of $\geq$3 g/dL, and blood transfusions were compared.

RESULTS A total of 169 patients (57% male, mean 83.7 years) underwent femoral closure with at least two PP followed by one AS. Complete hemostasis was obtained in 140 (83%) cases (Table). In the failure group, there were higher rates of hypertension (systolic aortic pressure 192±28 vs. 129±18 mmHg, $p=0.015$ and diastolic aortic pressure 68±11 vs. 42±15 mmHg, $p=0.050$).

CONCLUSIONS The utility of the AS technique when a pre-close PP strategy fails in patients with difficulty in femoral hemostasis after TAVR is feasible. Even when this strategy fails, hemostasis is achieved with conventional techniques without requiring surgery.

Characteristics	Success Group With Angio-Seal (n=140)	Failure Group With Angio-Seal (n=29)	p-Value
Manual compression	0% (0/140)	14% (4/29)	p<0.001
Additional closure device(s) prior to Angio-Seal	0% (0/140)	7% (2/29)	p=0.020
Balloon cross-over technique	15% (20/137)	29% (8/28)	p=0.009
Total access site percutaneous intervention	7% (7/107)	21% (6/28)	p=0.028
Access site surgical intervention	3% (3/107)	0% (0/29)	p=1.000
Decrease in hemoglobin of $\geq$3 g/dL	8% (9/107)	8% (2/25)	p=1.000
VARC-2 major and minor vascular complications	16% (22/133)	30% (8/27)	p=0.174
VARC-2 major and minor bleeding complications	11% (14/132)	15% (4/28)	p=0.220
Post-procedural blood transfusion	20% (27/135)	39% (11/28)	p=0.028